CERA-CHEK™ *Lactate*

User Manual

1 IMPORTANT SAFETY INSTRUCTIONS

- Please read the following instructions carefully before using the CERA-CHEK™ Lactate Measuring System.
- Close supervision is necessary when this testing device is used by children or patients.
- This product is intended for in vitro (external) use.
- Use only with CERA-CHEK™ Lactate Test Strip.
- Do not let the device come into contact with hot surfaces.
- Do not expose the device to dust or other contaminants.
- Avoid high humidity. This system may result in inaccurate measurements when used with high humidity.
- Stop using the system when there is an operational failure or damage to the product.

NOTE

Keep the user manual nearby the device and consult it whenever needed.

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3 INTRODUCTION

Thank you for choosing the CERA-CHEK™ Lactate Measuring System.
The CERA-CHEK™ Lactate measures accurately and quickly the concentration level of lactate in your blood. It measures your lactate level with as little as 1 ㎕ of blood within 10 seconds. Please read the manual thoroughly and be acquainted with the purpose of the product and how to use and maintain it before you start using the system.

3-1. Intended Use

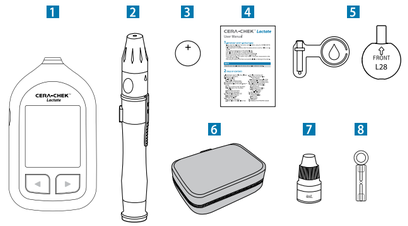
The CERA-CHEK™ Lactate Measuring System is intended to help people manage their lactate level. It also provides healthcare professionals with helpful information by measuring Lactate in fresh capillary whole blood as well as venous blood. The CERA-CHEK™ Lactate Test Strip is intended for in vitro diagnostic use.

3-2. Principle of Measurement

The CERA-CHEK™ Lactate Test Meter analyzes the Lactate levels employing an electrochemical method. Electric current occurs when lactate in blood reacts with the reagent of the test strip. The system converts the generated electric current to a lactate measure using a mathematical formula equipped in the meter and it shows you the converted lactate measure.

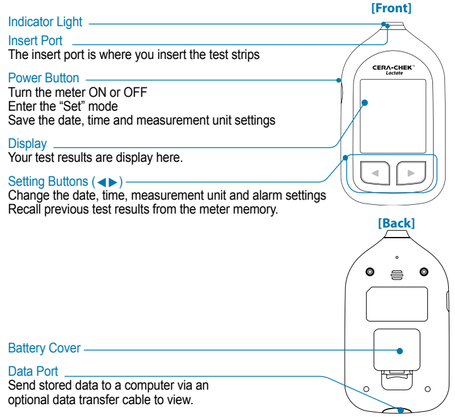
4 CONTENTS OF THE SYSTEM

① Test Meter
② Lancing Device
③ 3V Lithium Coin Battery
④ User Manual
⑤ CERA-CHEK™ Lactate Test Strips and Code key (Sold Separately)
⑥ Carrying Case
⑦ Lactate Control Solution (Sold Separately)
⑧ Sterile Lancet (Optional)

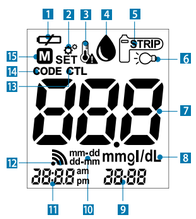


5 UNDERSTANDING THE CERA-CHEK™ Lactate

5-1. Key Functions of the Test Meter

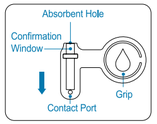

[Front]
Indicator Light
Insert Port
The insert port is where you insert the test strips
Power Button
Turn the meter ON or OFF
Enter the "Set" mode
Save the date, time and measurement unit settings
Display
Your test results are display here.
Setting Buttons (◀▶)
Change the date, time, measurement unit and alarm settings
Recall previous test results from the meter memory.
[Back]
Battery Cover
Data Port
Send stored data to a computer via an optional data transfer cable to view.

5-2. Explanation of the Test Meter Display



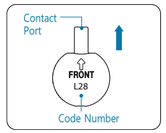
1 Battery Symbol : Appears when the battery is low
2 Set Symbol : Appears when in the set mode
3 Temperature Symbol : Appears when the temperature is abnormally high or low
4 Blood Symbol : This symbol tells you when to apply the sample
5 Test Strip Symbol : Appears when the meter is on and it indicates to insert the test strip
6 Indicator Light Symbol : Appears when the indicator is setting
7 Test Result Area : Displays test result or error messages
8 Measurement Unit : Appears with the test result either in mmol/L or mg/dL
9 Displays Date, or the Number of Test Results
10 Day/Month Format
11 Displays Time
12 Sound Symbol : Appears when sound is setting
13 Control Result Marker : Indicates the result was tested with Lactate Control Solution
14 Code: Appears with the code number of the test strip
15 Memory Symbol : Appears when the meter is on the memory mode

5-3. Test Strip Description



Contact Port : Insert this end of the test strip into the test meter. Push it in firmly until it will go no further.
Grip : Hold this part to insert or remove the test strip.
Confirmation Window : This is where you confirm if enough blood has been applied to the absorbent hole of the test strip.
Absorbent Hole : Apply a drop of blood here. The blood will automatically flow into the reaction zone.

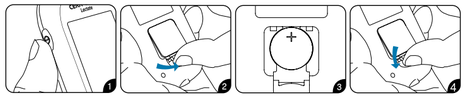
5-4. Code Key Description



When using the CERA-CHEK™ Lactate Measuring System for the first time, or before using a new box of test strips, you will need to calibrate the test meter. The code key must match the code numbers on the test strip vial and LCD display.
Please check the right direction to insert the code key into the test meter.

6 PREPARATION BEFORE USE

6-1. Changing the Battery



① Make sure the meter is off before removing the battery.
② Pull the buckle on the battery cover and pull the cover forward.
③ Insert a new 3V lithium battery(CR 2032) with the positive (+) sign facing up.
④ Close the battery cover.

CAUTION

Replacing the battery will not delete test meter settings unless you:
- Touch the metal wire inside the battery unit with your fingers or with another metal
- Load the battery incorrectly
- Load a used or weak battery

WARNING

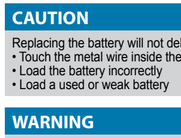
- Keep away all batteries from children's reach.
- If a battery is swallowed, please consult a doctor immediately.

NOTE

- To save battery power, the test meter automatically turns off after 2 minutes of inactivity.
- When the low battery symbol appears with other displayed data, it means the battery is running low but has enough power to run 20 times. It is recommended that you should replace the battery as soon as possible. The battery symbol will only appear if the battery is too low to perform any more blood lactate tests. The meter will not function until the battery is replaced.
- Discard old battery as per guidelines.
- Recheck and reset the clock setting as necessary after battery replacement to ensure time is set correctly. To set the meter clock, see Test Meter Set-up on the next section.

6-2. Test Meter Set-up

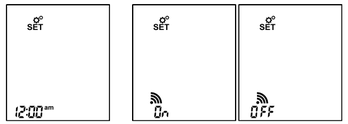
The meter will enter the set mode when replace the battery. With your meter turned on press the Power button for 3 seconds to enter the set mode.
To exit the set mode in any step of the setting, press the Power button for 3 seconds. The meter will save the settings and it will turn off.



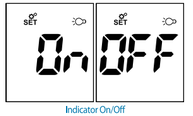
1) Set Year: The year will appear at the bottom of the display. Press the Setting buttons (◀▶) until the correct year is displayed. Once you have selected the correct year, press the Power button to save your choice and start setting the month.
2) Set Month: The month will appear at the bottom of the display. Press the Setting buttons(◀▶) until the correct month is displayed. Once you have selected the correct month, press the Power button to save your choice and start setting the day.
3) Set Day: Press the Setting buttons(◀▶) until the correct day is displayed. Once you have selected the correct day, press the Power button to save your choice and start setting the hour.

NOTE

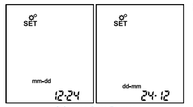
Pressing the Setting buttons(◀▶) continuously will pass the numbers quickly.



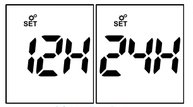
4) Set Hour: Press the Setting buttons(◀▶) until the correct hour is displayed. Once you have selected the correct hour, press the Power button to save your choice and start setting the minutes.
5) Set Minute: Press the Setting buttons(◀▶) until the correct minute is displayed. Once you have selected the correct minute, press the Power button to save your choice and start setting the alarm.
6) Set Sound: Press the Setting buttons(◀▶)to select to turn On or Off the Sound. After selecting the Sound On or Off on the display, press the Power button to start setting the Indicator light On/Off.



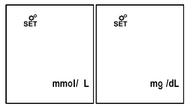
7) Set Indicator: Press the Setting buttons (◀▶) to select to turn On or Off the Indicator light. With the indicator On, the indicator light located on the insert port will be blinking and vice versa. After selecting the Indicator On or Off on the display, press the Power button to save your choice and start setting the date format.



8) Set Date Format : Press the Setting buttons (◀▶) until the desired date format is displayed. Once you have selected the desired date format, press the Power button to save your choice and start setting the time format.



9) Set Time Format: Press the Setting buttons (◀▶) until the desired time format is displayed. Once you have selected the desired time format, press the Power button to save your choice and start setting the measurement unit.



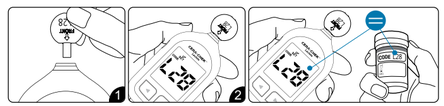
10) Set Measurement Unit : Press the Setting buttons(◀▶) to select the measurement unit (mg/dL or mmol/L). With the correct measurement unit on the display, press the Power button to save your choice and complete all the setting.

TIP

In set mode, the system will automatically turn off if it is not used for 2 minutes.

7 BEFORE TESTING

7-1.Coding the Test Meter



Insert the code key completely into the code key port with the code number facing up and the code number will appear on the LCD display. Make sure the code numbers on the display match the code key and the test strip vial. If all of the numbers match, you may begin testing.

NOTE

If the code numbers displayed on the screen do not match the code key and the test strip vial, try calibrating again or contact your local distributor.

7-2. Lactate Control Solution Test

Checking the System with Lactate Control Solutions:
The expected range printed on the test strip vial label, it is able to check that the test meter and the test strips are working together as a system and that you are performing the test correctly. It is very important that you do this simple check routinely to make sure you get accurate results.

Perform a Lactate Control Solution Test if:
- You are using the test meter for the first time.
- You suspect the test meter or test strips may not be functioning properly.
- Test results appear to be abnormally high or low, or are not consistent with the symptoms you are experiencing.
- The test strip vial was left open.
- You are using a new vial of test strips.
- You dropped the test meter.

NOTE

The results obtained from your Lactate Control Solution test do not indicate your personal Lactate levels.

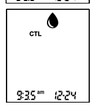
IMPORTANT

Use CERA-CHEK™ Lactate Test Meter only with CERA-CHEK™ Lactate Test Strips. Lactate Control Solution is sold separately. Do not use the control solution after expiration date as printed on the vial.

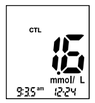
1) Insert the test strip into the insert port of the test meter
The blood symbol will start blinking.

2) Press the Setting button (◀or▶) to mark the test as a Lactate Control Solution test.
'CTL' symbol will appear on the display.

3) Prepare the Lactate Control Solution
Place the bottle(s) of control solution to be analyzed at room temperature (15 °C ~ 30 °C) for 20 minutes prior to use.
Make sure that the test meter, test strips and control solution are stabilized at room temperature before the test.
Mix thoroughly by gently inverting the bottle and rolling between the palms until all components are completely suspended.
Remove the cap from the bottle, tilt the bottle at a downward angle, and gently squeeze the bottle so that a drop forms.



4) Apply Lactate Control Solution
Aim directly at the absorbent hole of the test strip. Squeeze the vial again to get another drop and the drop will be automatically drawn in the test strip. Make sure the confirmation window is completely filled.The test meter will count down from 10 seconds and then display the Lactate Control Solution test result.
If the test result is out of the specified range printed on the test strip vial, repeat the control test. If you still have a problem, please contact your local distributor for assistance.



NOTE

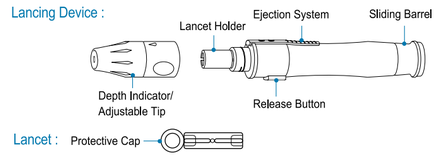
After each use, wipe the tip and threads of the bottle and cap. Replace the cap and immediately tighten.
Return the opened bottle(s) to the chosen open-bottle storage temperature immediately after use.

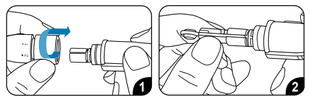
8 TESTING YOUR BLOOD

8-1. Getting a Drop of Blood from Fingertip

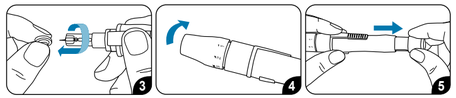
IMPORTANT

Please wash and dry your hands prior to starting.

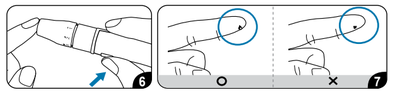




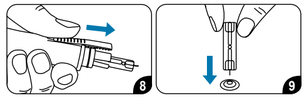
1) Screw off the cap of the lancing device.
2) Insert a lancet into the lancet holder and push down firmly until it is fully seated.



3) Twist the protective cap until it is separated from the lancet.
4) Replace the lancing device cap. Twist the adjustable tip in either direction until the desired number lines up with the arrow: 1~2 for soft of thin skin, 3 for average skin, 4~5 for thick or calloused skin.
5) Pull the sliding barrel until it clicks.



6) To get a drop of blood from a fingertip
Hold the lancing device firmly against the side of your fingertip.
Press the release button. You will hear a click, indicating that the puncture is complete.
7) Then gently squeeze the punctured area to obtain blood sample.
Do not smear the blood sample.



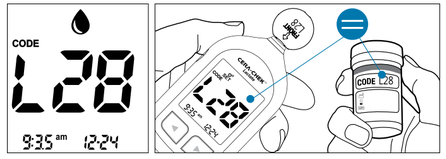
8) Remove the lancet After pulling the sliding barrel out.
Push the ejection system upwards to remove the lancet.
9) Place the protective cap on a hard surface and push the exposed tip into the protective cap.

WARNING

A lancet should only be used once. Please discard the used lancet.
A lancet should never be shared to avoid the risk of infection with another person.

8-2. Performing a Lactate Test

1) Insert test strip
Pick up the test strip from the vial and immediately close the cap. Insert the test strip into the insert port. The code number will appear and the 'blood' symbol (🩸) will blink on the display.



IMPORTANT

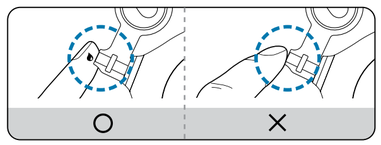
Make sure the code number shown on the display matches the code number printed on the test strip vial. If the code numbers are different, please refer to the section of '7-1. Coding the Test Meter', for the procedure of coding.

2) Obtain a blood sample
Please refer to the section of '8-1'. Getting a Drop of Blood from Fingertip.

3) Apply blood onto the test strip
Apply your blood to the absorbent hole of the test strip until the confirmation window is full of blood. The test meter will begin to count down from 10 seconds and a result will be displayed.

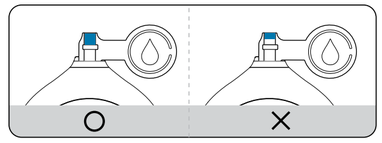
NOTE

If you do not apply a blood sample to the test strip within 2 minutes, the test meter will automatically shut down. You must remove and reinsert the test strip to restart the test procedure.



CAUTION

The blood sample should fully fill the confirmation window in order to get an accurate result. If you find that the confirmation window is not fully filled when the test meter is counting, DO NOT try to add more blood to the test strip. Discard the test strip and retest with a new one.



4) Obtain an accurate result in 10 seconds
The result of your blood lactate test is shown on the test meter display.
This reading is automatically stored in the test meter.

CAUTION

Please discard the used test strip immediately after use. DO NOT REUSE THE TEST STRIP.

9 MEMORY

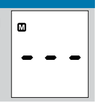
9-1. Reviewing the Memory

CERA-CHEK™ Lactate can store up to 1000 test records. Each record includes the test result, time and date.

Viewing Stored Records
With the meter On press one of the Setting buttons (◀▶) to enter memory mode.
First, you will see the test number, then it will switch to your test results with date and time.
The most recent test result and the memory symbol (Ⓜ) will appear on the display.
Press the Left arrow button(◀) to go through the stored records.

NOTE

If you are using the meter for the very first time, the meter display will show three dashed lines (—) and the 'memory' symbol (Ⓜ).This means that no data has been stored in memory.



NOTE

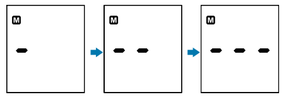
If there are already 1,000 records in the memory, the oldest record will be erased to make room for a new one. Your most recent result will display first.

If you press the Power button when viewing memory, the lactate meter will shut down.

9-2. Clearing the Memory

1) Press and hold both the Setting buttons(◀▶) for more than 3 seconds to enter the delete mode from the memory mode. You will see both displays "dEL" and "ALL" switching one after another.

2) To clear the memory, press and hold both the Setting buttons(◀▶) for 3 seconds. The display will show 'memory' symbol (Ⓜ) and "---", the meter will clear its memory and turn itself off after a moment.



3) If you entered the delete mode but want to exit without deleting the stored data, press the Power button. This will turn the meter off without deleting any data.

WARNING

Extreme caution should be used when clearing the memory. This is not a reversible operation.

9-3. Normal Lactate Range

Whole Blood (Capillary,Venous Blood) : 0.7~2.1 mmol/L')

Reference
1) Wallach, J. Interpretation of Diagnostic Tests 7th ed., p13, Brown and Company, Boston MA (2000)

10 TRANSFERRING STORED DATA

CERA-CHEK™ Lactate provides a comfortable function to our users. Lactate management software that can transfer and show analytical interpretation of all the stored data of lactate results from your test meter into your computer.

NOTE

To use the lactate management software, you should purchase separately the installation CD and USB data transfer cable.

1) Make sure the test meter is turned off.
(Data cannot transfer when the device is still on).
2) After you initiate the software for lactate management on the computer, you connect the transfer cable from the computer to the test meter .
3) If the connection is properly carried out, the test meter will display "PC" on the display screen.

NOTE

When you disable the cable during the transfer of data, the data may not be transferring properly. Please keep the transfer cable intact until the transfer is completed.

4) After the data transfer is completed, you can release the transfer cable.

In case you need more details about the lactate management software of CERA-CHEK™ Lactate, please contact your local distributor.

11 CARING FOR YOUR TEST METER AND TEST STRIPS

To avoid contaminating your test meter and test strips, please wash your hands and test site with soap and water. Make sure to dry your hands and test site thoroughly.

11-1. Maintenance

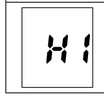
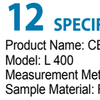
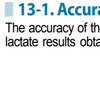
Your test meter does not require special maintenance. There is no special cleaning required because no blood or control solution comes in contact with the test meter. Avoid getting dirt, dust, blood, or water inside the test meter through the test port. A dry cloth and mild detergent can be used to wipe the outside of the test meter. Your test meter is a precision instrument. Please handle it with care.

11-2. Storage and Handling

1) Test Meter storage and handling
- Store test meter at : -10 °C ~ 60 °C (14 °F ~ 140 °F).
- Do not leave the test meter in very hot or cold places.
- Do not leave it near a heat source or in your vehicle during adverse weather conditions.
- Always store or carry the test meter in its original storage case.
- Avoid dropping and strong impact.
- Avoid direct sunlight and humidity.

2) Test Strip storage and handing
- Store test strips at 1 °C ~ 32 °C (34 °F ~ 90 °F), below 85 % relative humidity.
- Store your test strips in their original vial only. Do not transfer to other containers.
- Store test strips in a cool and dry place. Keep away from direct sunlight and heat.
- After taking test strips from the vial, close the vial cap.
- Touch the test strips with clean and dry hands.
- Use each test strips immediately after removing it from the vial.
- Write the disposal date on the test strip vial as a reminder to dispose of the opened vial after 4 months.
- Do not bend, cut, or alter a test strips in anyway.
- Keep the test strips away from children since the cap and the test strips may be a choking hazard. If swallowed, immediately see a doctor for help.
- Follow local governing ordinances and recycling plans for disposal or recycling of device components.

11-3. Error Message and Troubleshooting

Message	Possible cause	What You Should Do
	Test result level is over 25.0mmol/L (225.3mg/dL).	Repeat the test with a new test strip. If this message shows again, please contact your doctor immediately.
	Test result level is less than 0.5mmol/L (4.5 mg/dL).	Repeat the test with a new test strip. If this message shows again, please contact your doctor immediately.
	Prepare to replace the battery.	Recommending to replace the battery.
	The battery power is too low for testing.	Replace the battery at once.
	The operating temperature of the system is not the mentioned range. 4°C ~ 40°C (39°F ~ 104°F).	Allow the test meter and test strips to warm up or cool down slowly (30 minutes) until the error message goes away.
	Test strip is used.	Repeat test with a new test strip.
	Failure to operate during a test.	Repeat test with a new test strip.
	Test strip was removed during a test.	Repeat test with a new test strip.
	Damaged code key or the code key was removed during a coding the meter.	Re-coding the Test Meter If the problem still continues, please contact your local service center.
	The code is not set.	Insert the code key that accompanied the box of the test strips.

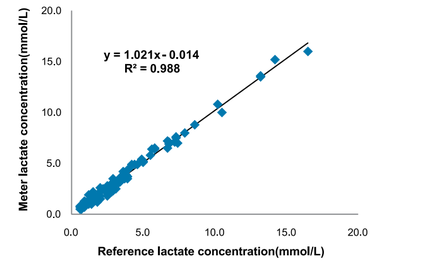
12 SPECIFICATIONS

Product Name: CERA-CHEK™ Lactate Measuring System
Model: L 400
Measurement Method: Electrochemical Method
Sample Material: Fresh whole blood from capillary and venous
Sample Size: 1.0 μl
Hematocrit Range: 20 % ~ 60 %
Test Time: 10 Seconds
Dimensions: 58 X 101.5 X 12.5(mm)
Measurement Range: 0.5 ~ 25.0mmol/L (4.5 ~ 225.3mg/dL)
Measurement Unit: Either mmol/L or mg/dL
Weight: 40g
Power Source: One CR 2032 3V lithium coin battery
Display: LCD
Memory: 1,000 measurement results with date and time
Automatic Turn Off: Shuts Down After 2 Minutes of Inactivity
Operating Condition: 4°C~40°C (39 °F~104 °F), below 85% relative humidity
Storage / Transport condition: -10~60°C (14~140°F), Below 85% Relative Humidity, 700~1060 hPa.

13 PERFORMANCE CHARACTERISTICS

13-1. Accuracy

The accuracy of the CERA-CHEK™ Lactate Test Strip was evaluated by comparing blood lactate results obtained from 100 people with replicate measurement. Readings obtained with the CERA-CHEK™ Lactate Test Strip was compared to those obtained using an YSI Model 2300 Lactate Analyzer.
The correlation obtained between the CERA-CHEK™ Lactate Measuring System results and reference device results was R^2=0.988, therefore CERA-CHEK™ Lactate Test Strip has shown high accuracy.



13-2. Precision

The precision of CERA-CHEK™ Lactate Test Strip was estimated with venous blood samples in the laboratory.

Lactate concentration (mmol/L)	STD (mmol/L)	CV (%)	n
3.1	0.16	5.1	60
9.1	0.23	2.5	60
16.1	0.22	1.3	60
22.2	0.37	1.7	60

14 WARRANTY

The manufacturer, CERAGEM MEDISYS Inc., guarantees the CERA-CHEK™ Lactate Measuring System to be free of defects in material and workmanship for a period of 3 years. This guarantee is valid from the date of purchase. The guarantee extends only to the original purchaser and is not transferable.

15 SYMBOLS FOR PROPER USAGE

Symbol	Referent
IVD	In vitro diagnostic medical device
	Do not reuse
	Consult instructions for use
	Temperature limitation
	Use by
	Date of manufacture
LOT	Batch code
	Manufacturer
SN	Serial Number
	Power Button
EC REP	Authorized representative in the European community
	Do not dispose the instrument with the urban waste
	Caution, consult accompanying documents
	Direct current
CE 0123	This product fulfills the requirements for directive on in vitro diagnostic medical devices.

CERAGEM MEDISYS Inc.
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